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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/841,609	04/25/2001	Vitaliy Arkadyevich Livshits	206339US0	4787

22850 7590 10/01/2003

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EXAMINER
KERR, KATHLEEN M

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 10/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/841,609	LIVSHITS ET AL.	
	Examiner	Art Unit	
	Kathleen M Kerr	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 July 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4 and 6-12* is/are pending in the application.

4a) Of the above claim(s) *1-3 and 8* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *4,6,7 and 9-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Application Status

1. In response to the previous Office action, a non-Final rejection (Paper No. 10, mailed on March 10, 2003), Applicants filed a response and amendment received on July 10, 2003 (Paper No. 13). Said amendment cancelled Claim 5, amended Claims 4, 7, and 8 and added new Claims 9-12. Thus, Claims 1-4 and 6-12 are pending in the instant Office action.

Election

2. Claims 1-4 and 6-12 are pending in the instant application. Claims 1-3 and 8 are withdrawn from further consideration as non-elected inventions. Claims 4, 6, 7, and 9-12 will be examined herein.

This application contains claims 1-3 and 8 drawn to an invention nonelected with traverse in Paper No. 9. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 C.F.R. § 1.144) See M.P.E.P. § 821.01.

Priority

3. As previously noted, the instant application is granted the benefit of priority for the foreign application 2000110350 filed on April 26, 2000 in Russia. No translation of the priority document has been received.

Withdrawn - Objections to the Specification

4. Previous objection to the specification because the title is not descriptive is withdrawn by virtue of Applicants' amendment.

5. Previous objection to the Abstract for not completely describing the disclosed subject matter is withdrawn by virtue of Applicant's amendment.

Withdrawn - Objections to the Claims

6. Previous objection to Claim 4 for a typographical error is withdrawn by virtue of Applicants amendment.

7. Previous objection to Claim 7 under 37 C.F.R. § 1.75(c) as being in improper form because a multiple dependent claim cannot depend from another multiple dependent claim is withdrawn by virtue of Applicants' amendment.

New or Maintained - Claim Rejections - 35 U.S.C. § 112

8. Previous rejection of Claims 4 and 6-7 under 35 U.S.C. § 112, second paragraph, as being indefinite for the term "sucrose non-PTS genes" is maintained; Claims 9-12 are added to the instant rejection. Applicants' arguments have been fully considered but are not deemed persuasive. Applicants argue that the amendment has clarified the claim, but this is not the case. As previously noted, the specification described sucrose non-PTS genes by way of example from Bockmann *et al.* (see page 4) in which a csc regulon is described encompassing cscB (a permease), cscK (a fructokinase), cscA (an invertase), and cscR (a repressor) (see Fig. 2). It is not clear if this regulon (Bockmann *et al.*) must be used or if any csc-type regulon, which can be considered sucrose non-PTS genes, can be used. Moreover, are the named "permease, invertase, and fructokinase" particularly permeases, invertases, and fructokinases that are sucrose non-PTS

genes or can any permease, invertase, and fructokinase meets the limitations of the claims? Clarification is required so that the metes and bounds of the instant claims can be determined.

9. (New) Claims 9-12 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "csc genes" is unclear. On page 7, the specification notes that csc genes can be obtained from *E. coli* EC3132; however, it is unclear if this is the only source. If not, then what are the criteria of being a csc gene? If one looks to the art for definition, again the claims are unclear. Sahin-Toth *et al.* (as supplied by Applicants) describe a sucrose-hydrolase invertase gene 98% identical to cscA of Bockmann *et al.* (see pages 418-419); however, no related permease and fructokinase genes are noted. Must an entire regulon be used or can one piecemeal a regulon together from known genes? If piecemeal is acceptable, then, again, one of skill in the art must be able to identify a csc permease or a csc fructokinase that can work together with a csc invertase to be considered sucrose non-PTS genes. Clarification is required so that the metes and bounds of the instant claims can be determined.

10. Previous rejection of Claims 4 and 6-7 under 35 U.S.C. § 112, first paragraph, written description, is maintained; Claims 9-12 are added to the instant rejection. Applicants' arguments have been fully considered but are not deemed persuasive. Applicants argue that the specification, in combination with the art, adequately describes sucrose non-PTS genes of permease, invertase, and fructokinase function using 4 papers; only one of these papers cites genes, as required by the claim. This paper, Sahin-Toth *et al.*, describes an example of a csc gene that is a sucrose-hydrolase invertase from *E. coli*. Thus, the only sucrose non-PTS gene

described other than that of Bockmann *et al.* as noted in the specification, is a single invertase gene of a function more specifically denoted than described in the specification. Moreover, the gene of Sahin-Toth *et al.* is also from *E. coli*; no other species are, thus, represented. This limited description in the specification and the art does not adequately describe the claimed genus. Thus, in view of the specification and the art, one of skill in the art would be unable to predict the structure of the genes in the genus claimed.

11. Previous rejection of Claims 4 and 6-7 under 35 U.S.C. § 112, first paragraph, scope of enablement, is maintained; Claims 9-12 are added to the instant rejection. Applicants' arguments have been fully considered but are not deemed persuasive for the following reasons. Applicants argue that a "person skilled in the art can easily obtain genes of the above sucrose non-PTS by conventional methods; however, the ability to ---find--- does not satisfy the ability to "make" as required by the statute. The Examiner agrees that if one of skill in the art knew a particular strain harbored a csc regulon, such DNA could be isolated using the methods of Bockmann *et al.* The claims are enabled for such methods (although description is a problem as noted above); this is a scope of enablement rejection that is maintained. However, identification of such trains is limited in the art (see Keevil *et al.* 1984, Jacobson *et al.* 1989, and Slee *et al.* 1982 as described by Applicants). Thus, the instant claims are not enabled to the full extent of their scope.

Withdrawn - Claim Rejections - 35 U.S.C. § 101

12. Previous rejection of Claims 4-7 under 35 U.S.C. § 101 is withdrawn by virtue of Applicants' amendment.

Maintained - Claim Rejections - 35 U.S.C. § 102

13. Previous rejection of Claims 4 and 6-7 under 35 U.S.C. § 102(b) as being anticipated by Bockmann *et al.* is maintained; Claims 9-12 are added to the instant rejection. Applicants' arguments have been fully considered but are not deemed persuasive for the following reasons. Applicants argue that because Bockmann *et al.* do not expressly teach that the *E. coli* JM109 harboring plasmid pJMBL102 accumulates amino acids in the media, the claims are not anticipated. Accumulation of amino acids in the media is an inherent feature of *E. coli*; no requirement on the amount of accumulation is in the limitations, thus any accumulation meets the limitations of the claims. *E. coli* are known producers of amino acids in manufacturing (see Burkovski *et al.* Bacterial amino acid transport proteins: occurrence, functions, and significance for biotechnological applications. Appl Microbiol Biotechnol. 2002 Mar;58(3):265-74).

Applicants also argue that "the bacterium of the present invention can produce an amino acid in higher yield"; this fact is useful, however, it is not a claim limitation and thus, no relevant to the anticipation of the claims by Bockmann *et al.*

Additionally, the Examiner notes that, in the absence of clear claim language, the claimed *Escherichia* bacteria need only have a gene for a permease, an invertase, and a fructokinase. In the case of Bockmann *et al.*, JM109 inherently has genes encoding these proteins (no requirement for transformation of the permease, etc. is required by the claim language). Thus, any *Escherichia* cell that produces amino acids in the media meets the limitations of the claim.

Response to Arguments

14. Applicants remarks contain a paragraph discussing USPN 5,672,663, which discussion does not seem to be related to any particular rejection but to the allowability of the claims overall. Applicants note that the patent "related to the use of efflux genes" and "mentions" particular loci while the claims "appear to embrace all proteins directly suitable for secreting toxic substances". The Examiner is unable to comment on the particular scope allowed in another patent, particularly with respect to wholly different subject matter (secretion of toxic substances vs. sucrose assimilating genes in the instant application), accept to say that the claims of USPN 5,672,663 are adequately described and fully enabled in view of the specification and the art at the time of the invention. This is not the case for the instant claims in view of the specification and the art as noted above.

Summary of Pending Issues

15. The following is a summary of the issues pending in the instant application:

a) Claims 4, 6-7, and 9-12 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the term "sucrose non-PTS genes".

b) Claims 9-12 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for the term "csc genes".

c) Claims 4, 6-7, and 9-12 stand rejected under 35 U.S.C. § 112, first paragraph, written description.

d) Claims 4, 6-7, and 9-12 stand rejected under 35 U.S.C. § 112, first paragraph, scope of enablement.

e) Claims 4, 6-7, and 9-12 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Bockmann *et al.*

Conclusion

16. Claims 4, 6-7, and 9-12 are not allowed for the reasons identified in the numbered sections of this Office action. Applicants must respond to the objections/rejections in each of the numbered sections in this Office action to be fully responsive in prosecution.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (703) 305-1229. The examiner can normally be reached on Monday through Friday, from 8:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (703) 308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

KMK
September 25, 2003

PONNATHAPU ACHUTAMURTHY
SUPERVISORY PATENT EXAMINER
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